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CTFA
Cosmetic, Toiletry, and Fragrance Association

July 19, 2005

Pamela G. Bailey
President & CEO

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 1998N-0359; Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

Dear Sir or Madam:

The following comments are submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") in response to the request for comments on Program Priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for Fiscal Year 2006 (October 1, 2005 to September 30, 2006). 70 Fed. Reg. 29328 (May 20, 2005). Our comments are focused on the priorities for CFSAN related to its responsibility for cosmetic regulation and enforcement.

CTFA is the national trade association representing the cosmetic industry. Founded in 1894, CTFA has almost 600 members involved in formulating, manufacturing, distributing and marketing personal care products. Our members are responsible for manufacturing or distributing the vast majority of personal care products sold in the United States.

The U. S. cosmetic industry has an enviable safety record, built on the strong foundation of the industry's commitment to safety backed by the authority of FDA to act quickly and effectively should there be any question regarding the safety of an ingredient or product. The foundation of the safety net for these products is the Cosmetic Ingredient Review which, with FDA's participation on the Expert Panel, reviews and publishes findings regarding the safety of cosmetic ingredients.

In the past year, the validity and effectiveness of CIR and the FDA regulatory system of cosmetics has been challenged both in a petition submitted by the Environmental Working Group to FDA and in state legislation sponsored by the same group intended to increase the authority of the California state government for regulating cosmetics. This has received significant publicity, and we are concerned that, over time, such public attacks could result in unwarranted questions among consumers regarding the safety of their cosmetic products. We

believe the Agency should share that concern, and we call upon FDA to work with the industry to ensure that the combination of FDA's regulatory authority and the industry's key safety programs are as strong as they need to be to ensure public confidence in the safety of cosmetic products sold in the United States.

It is equally important that FDA remain the preeminent national authority to regulate cosmetics, and that regulatory standards remain uniform throughout the United States. Although we believe FDA has the authority to preempt inconsistent state regulations, the likelihood that states will attempt to interfere with FDA's jurisdiction and that such action will be necessary is lessened by strong action by FDA to clarify and, if necessary, implement its existing regulatory authority now.

Therefore, we suggest one "A" list priority for FY2006 that we believe should be the central focus of the Office of Cosmetics and Colors and should be fully supported by CFSAN.

Working with the Expert Panel Findings of the Cosmetic Ingredient Review, clarify and implement as necessary FDA enforcement authority to ensure the safety of Cosmetic products

We believe that such action is consistent with the February 3, 2005 letter of Center Director Dr. Robert Brackett in which he stressed the seriousness with which FDA takes its effort "to ensure that the products we regulate, including cosmetics, are safe" and further emphasized the importance of the role of the Cosmetic Ingredient Review in determining the safety of cosmetic ingredients. Among the steps that should be taken to achieve this priority are the following:

1. Respond to the Citizen Petition filed by the Environmental Working Group questioning the safety of cosmetic products. We believe there are many flawed allegations in the EWG Petition, but we also believe it is important that the Agency respond to the petition in a timely manner, and, if necessary, establish a process by which interested parties can comment on any issues that FDA believes are significant. This was an "A List" priority in FY2005. We urge FDA to complete this process as soon as possible.

2. Develop a Guidance for Implementation of 21 CFR 740.10. This provision of FDA regulations requires a manufacturer to substantiate the safety of each cosmetic ingredient and the finished cosmetic products or to place a warning on the principal display panel of its product stating – Warning: The safety of this product has not been determined. Such an effort was a "B List" priority for FY2005. We believe it needs to be upgraded to an "A List" priority

for 2006 and given the resources necessary to be completed as soon as possible.

Implementation of 21 CFR 740.10 is an important element of the FDA's authority to lend force and credibility to the findings of the CIR Expert Panel. Obviously, FDA should take action when an ingredient is used that has been found to be unsafe for use in cosmetic products. In addition, when an ingredient is used in ways that fall outside the limits of safe use, or an ingredient is used that FDA believes may have insufficient data to determine safety, the Agency should determine whether a company has data to support use of the ingredient and, if not, to enforce the 740.10 warning requirement. In each circumstance, we would anticipate that FDA would look to the findings of the CIR Expert Panel in determining whether the use of a particular ingredient would require further investigation by FDA and possible implementation of 740.10 warning requirements.

It is important that a guidance be established that will signal clearly to both the public and the regulated industry how FDA will proceed in such a case both in terms of setting priorities for action and in determining the procedures that will be followed to analyze any further available data before determining whether a 740.10 warning is required. CTFA is currently working with its members to develop a proposed Guidance that would achieve those objectives for the Agency's consideration.

3. Work with CTFA to Ensure that CIR and the Variety of Industry Voluntary Programs Provide the Strongest Possible Safety Net for Consumers – This will include efforts to strengthen the Voluntary Cosmetic Reporting Program, an activity that has received attention from FDA but not as high a priority as necessary in recent years, and a regular consultation with the CTFA and other interested parties on whether any other programs are necessary to supplement FDA's regulatory authority and resources.

Recognizing that the Center has serious resource constraints, we have deliberately limited our proposals to those which we think are most important in addition to the normal day-to-day activities of the Agency in ensuring the safety of cosmetic products. However, there is one additional action that we believe will strengthen the credibility and authority of FDA worldwide, and enhance the possibility of global harmonization of industry standards. This also should be an "A List" Priority to be implemented as quickly as is consistent with completing the cosmetic safety initiatives outlined above. This also is an activity for which CTFA will provide all support desired by the Agency.

Participate in International Efforts to Harmonize Standards For Cosmetic and Cosmetic-Drug Products

We have suggested that CFSAN harmonization efforts be extended to cosmetic-drugs such as sunscreens because these products are regulated as cosmetics in the European Union and much of the rest of the world. We support FDA's efforts to revitalize the "CHIC" (Cosmetic Harmonization and International Cooperation) efforts with the European Union, Canada, and Japan. We believe, at a minimum, that these efforts should be accelerated in FY2006 to determine if progress can be made to harmonize standards and facilitate the efforts of our industry to sell the same products across international boundaries.

To be successful, these efforts at international harmonization need not only participation but leadership from FDA. These efforts can not only eliminate unnecessary barriers to international marketing of cosmetic products, but also help to reduce the confusion about which jurisdiction's standards lead to safer products. This confusion is currently fueling ill-considered legislation in California and other states.

Conclusion

We appreciate the opportunity to comment on CFSAN's FY2006 Program Priorities, and look forward to supporting the Agency in the implementation of all of the matters discussed above. Please feel free to contact us if you have questions or need more information.

Respectfully submitted,

Pamela G. Bailey
President & CEO

cc: Robert E. Brackett, Ph.D.
Linda Katz, M.D.